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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,087	12/06/2004	Christian von Falkenhausen	RO0937US (#90568)	1143
7590 D Peter Hochberg Company 6th Floor 1940 East 6th Street Cleveland, OH 44114			EXAMINER SUTTON, DARRYL C	
			ART UNIT	PAPER NUMBER
			1612	
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			01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,087

Applicant(s)

FALKENHAUSEN ET AL.

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-29 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 11/17/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Election/Restrictions

Applicant argues that since Examiner acknowledges that Groups I and II possess a single inventive concept that Group III the method of manufacture of the products of Groups I and II also possesses the same inventive concept.

The Examiner disagrees. Groups I and II are drawn to a film like preparation, whereas Group III is drawn to active steps of manufacture, i.e. determining peroxide number, selecting formulation components, preparing a solution, and coating the solution. Therefore, it does not possess the same special technical feature of Groups I and II.

Applicant also argues that claims 13, 15-18 and 27-29 should be withdrawn rather than claims 13-18 and 24-29, i.e. claims 14 and 24-26 should not have been withdrawn.

The Examiner disagrees. Applicant made an election of a cellulose derivative for species (d) at least one polymer, See Response to Election Restriction, 03/07/2008.

Therefore, claims 24-26 which are drawn to water-soluble polysaccharide polymers and to proteins are correctly withdrawn from examination.

Regarding claim 14, "use" claim per se is nonstatutory. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Were claim 14 in proper form for examination, however, the examiner would agree with applicant's comments regarding same. Accordingly, in the interest of compact prosecution the Examiner will rejoin claim 14 once Applicant has rewritten it in proper form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-12 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theobald et al. (WIPO 01/080837, U.S. Patent Pub. 2003/0049308 provided for translation purposes) in view of Muller (WIPO 01/39753, U.S. Patent 6,699,498 provided for translation purposes) and Maierhofer et al. (US 5,853,753).

Theobald et al. teach a transdermal or transmucosal administration form comprising nicotine (Abstract, paragraphs [0001] and [0012]), i.e. the TTS of the invention provides equivalent transdermal and transmucosal delivery. In its simplest embodiment, the active substance reservoir of the transdermal therapeutic system,

TTS, is a single-layer polymer matrix; the matrix may further comprise auxiliaries and additives, especially additives which promote skin permeation, i.e. permeation enhancers (paragraphs [0023] and [0025]). The base of the TTS it is preferred to use cellulose derivatives, acrylate copolymers, polyvinylpyrrolidone, or polyvinyl acetate [0024] A transmucosal form of the invention comprising nicotine is preferably designed as a flat, film-like carrier and is provided with mucoadhesive properties, which are brought about through the addition of carboxymethylcellulose, hydroxypropylcellulose, ethylcellulose or propylcellulose [paragraph [0031]].

Theobald et al. does not teach the limitation of "peroxide number" or that the invention is further comprised of antioxidants.

Muller teaches a transdermal therapeutic system (TTS) in which the formation of oxidative degradation products of the oxidation sensitive active substance present is reduced during storage; this objective is achieved by using only those formulations constituents which are substantially free of hydroperoxides (column 6, lines 7-15). TTS may be differentiated into matrix systems and reservoir systems, where the active ingredient is particularly sensitive to reactions which lead to an impairment of stability; the simplest case the active substance is dissolved in a self-adhesive layer, i.e. film-like (column 1, lines 5-25). The stability of the active substance and of auxiliaries may be put at risk by reaction with active oxygen. Raw materials used to produce TTS may to a considerable extent comprise active oxygen in the form of hydroperoxides (column 1, lines 57-60, column 2, lines 48-57). Free-radical scavengers, antioxidants, such as tocopherol and its derivatives remove or inactivate free radicals; and interfere with

autoxidation reactions, i.e. degradation, reduction in stability (column 2, lines 33-42). Additional improvement of stability is achieved by the addition of antioxidants (column 7, lines 10-13). The TTS of the invention have a peroxide number of not more than 5 (column 6, lines 15-19, column 7, lines 14-17). They include as building blocks of a single-layer matrix, polymers, such as polyacrylates, polymethacrylates, and PVP; and functional additives or auxiliaries, such as permeation enhancers (column 6, lines 24-44). If the constituents are loaded with considerable amounts of hydroperoxides, these substances need to be substantially freed from hydroperoxides prior to use by reducing them in strong reducing substances, including organic sulfites such as sodium bisulfite and sodium hydrogen sulfite (column 6, lines 44-67, column 7, lines 32-36). Following this treatment, the materials are virtually free from peroxides (column 7, lines 8-10).

Muller does not teach a film-like preparation comprised of nicotine or transmucosal application.

Maierhofer et al. teach that octyl gallate, butylhydroxyanisol, butylhydroxytoluene and sodium sulfite are all physiologically tolerated antioxidants in concentrations of 0.01% to 2% by weight (column 3, lines 66-77 through column 4, lines 1-11)

Maierhofer et al. do not teach a film-like preparation comprised of nicotine.

It would have been obvious to modify the invention of Theobald with the antioxidant of Mueller motivated by the desire to improve the stability as taught by Mueller.

It would have also been obvious to modify the constituents of the invention of Theobald et al. by reducing them with the sodium hydrogen sulfite of Muller prior to use,

motivated by the desire to lower the peroxide number to 5 by removing peroxides which improves the stability as taught by Muller.

It is prima facie obvious to select a compound based on its suitability for its intended use. Therefore, it would have been obvious to use octyl gallate, butylhydroxyanisol, butylhydroxytoluene or sodium sulfite as an antioxidant in the composition suggested by combining Theobald et al. and Mueller.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612